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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/776,010	02/02/2001	Gregory Bruce Wilson	0179/61248-A/JPW/BJA	7419	
75	90 03/24/2006		EXAMINER		
Cooper & Dunham LLP			LI, BAO Q		
1185 Avenue of the Americas New York, NY 10036			ART UNIT	PAPER NUMBER	
11011 10111, 111 1			1648		
				DATE MAILED: 03/24/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

	LA - P - A - N		
, ••	Application No.	Applicant(s)	
Office Antique Commence	09/776,010	WILSON ET AL.	
Office Action Summary	Examiner	Art Unit	
<u> </u>	Bao Qun Li	1648	
The MAILING DATE of this community Period for Reply	unication appears on the cover sheet	with the correspondence addr	ess
A SHORTENED STATUTORY PERIOD WHICHEVER IS LONGER, FROM THE  - Extensions of time may be available under the provision after SIX (6) MONTHS from the mailing date of this cor  - If NO period for reply is specified above, the maximum  - Failure to reply within the set or extended period for reply any reply received by the Office later than three month earned patent term adjustment. See 37 CFR 1.704(b).	MAILING DATE OF THIS COMMUIns of 37 CFR 1.136(a). In no event, however, may numerication.  Statutory period will apply and will expire SIX (6) Not will, by statute, cause the application to become after the mailing date of this communication, even	NICATION.  y a reply be timely filed  IONTHS from the mailing date of this commendate ABANDONED (35 U.S.C. § 133).	
Status			
Disposition of Claims  4)  Claim(s) 32,33,36-40,42,43,46 and 4a) Of the above claim(s) is 5) □ Claim(s) is/are allowed.  6)  Claim(s) 32-33, 36-40, 42-43, 46-47) □ Claim(s) is/are objected to.  8) □ Claim(s) are subject to rest  Application Papers  9) □ The specification is objected to by 10) □ The drawing(s) filed on is/ar Applicant may not request that any ob Replacement drawing sheet(s) includi	2b) ☐ This action is non-final.  In for allowance except for formal matrice under Ex parte Quayle, 1935 Cod 47 is/are pending in the application are withdrawn from consideration.  If is/are rejected.  In it is a rejected in a requirement.  In it is a rejected or b is a required if the drawing the correction is required if the drawing the correction is required if the drawing the correction is required if the drawing the required if the drawing the correction is required in the correction is the correction is required in the correction is require	to by the Examiner.  yance. See 37 CFR 1.85(a).  ing(s) is objected to. See 37 CFR	: 1.121(d).
11) ☐ The oath or declaration is objected	to by the Examiner. Note the attacr	ied Office Action or form PTO	-152.
<ul><li>2. Certified copies of the priorit</li><li>3. Copies of the certified copie</li></ul>	by documents have been received. By documents have been received in a softhe priority documents have be ional Bureau (PCT Rule 17.2(a)).	n Application No en received in this National St	tage
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review  3) Information Disclosure Statement(s) (PTO-1449 Paper No(s)/Mail Date	(PTO-948) Paper N	w Summary (PTO-413) No(s)/Mail Date of Informal Patent Application (PTO-1	52)

Art Unit: 1648

#### **DETAILED ACTION**

## Response to the amendment

The is to acknowledge the amendment filed on Feb. 16, 2006. Claims 32-33, 36-40 and 46 have been amended. Claims 32-33, 36-40, 42-43, 46-47 are pending.

#### **RCE**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/16/2006 has been entered. An action on the RCE follows.

## Declaration under 37 C.F.R § 1. 132

The Declaration by Gregory B. Wilson filed on Feb. 16, 2006, has been acknowledged. And considered. However, it is not found persuasive for place the claimed invention in condition for allowance for the reasons in that the HHB6A and HHB6B TF and the method for making and purification of said antigen specific TF are already known was already known prior to the current application was filed. While the claims are now amended, the claimed inventions are still considered to be obvious for the person with ordinary skill in the art to be motivated to do so absence unexpected results in view of the disclosures in the prior art. The detail office action will explain set forth below:

# Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

Application/Control Number: 09/776,010

Art Unit: 1648

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Page 3

- 2. Claims 32-33, 36-40, 42-43 and 46-47 are still rejected under 35 U.S.C. 103(a) as being unpatentable over by Wilson et al. (Patent No. 4,816, 563) and Ablashi et al. (Biotherapy, 1996, Vol. 9, pp. 81-86).
- 3. Applicants traverse the rejection and submit an argument plus an declaration by Mr. Wilson, applicants asserted that the prior art does not teach or suggest the claimed invention. The rejection should be withdrawn. In particular, applicants submit that prior the application was filed there is no suggestion that the composition can be made by purification of TF from the milk product in which the colostrums and other factors, such as casein and fat would have been removed, and it does not teach why the TF is isolated from a bovine immunized with HHV-6A or HHV-6B.
- 4. Applicants' argument has bee fully considered; however, it is not found persuasive because the references cited by the office clearly teach both the method for purification of antigen specific TF and motivation why the other substances need to be removed from the TF composition (See all claims in patent 4,1816,563). The reference of Ablashi et al. also teach the motivation why the HHV6A and HHV6B TF is particularly interest because HHV6A and HHV6B specific TF can be used for treating chronic fatigue syndrome and mechanism why the HHV6A and HHV6B antigenic specific TF can be used fro treating chronic fatigue syndrome. Therefore,
- 5. Hence, the claimed invention as a whole is prima facie obvious absence unexpected results.
- 6. Claims 32-33, 36-40, 42-43 and 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Advertisement by Chisolm Biological Laboratory in Positive Health News Report No. 17, Fall Issue 1998, p 29) in view of Advertisement by Chisolm Biological Laboratory in Positive Health News, Fall, 1997, p. 27) and EP (0 143,445).
- 7. Applicants traverse the previous 102 rejection and submit that the cited references either alone or in combination does not teach every limitations of claimed invention. Moreover,

Page 4

Application/Control Number: 09/776,010

Art Unit: 1648

applicants argue that according Wilson' declaration, there is no suggestion at the application was filed that the composition can be made by purification of TF from the milk product in which the colostrums and other factors, such as casein and fat would have been removed and the motivation why the HHV6A and HHV6B TF is particular interest.

- 8. Applicants' argument has bee fully considered; however, it is not found persuasive because the massager delivered by the advertisement clearly indicates that the ImmunFactor can be made from the milk product, which is not a simply dried colostrums/whey products and it is a particular colostrums product comprising an antigen specific transfer factor with antigenic specific to HHHA6A and HHA6B which is at least in the preparation.
- 9. Moreover, the function of the HH6A and HH6B antigen specific TF has been known in the art prior to the application was filed for treating CFS patients and MS patients as evidenced by Chisolm Biological Laboratory in Positive Health News, Fall, 1997, p. 27).
- 10. Furthermore, prior to the current application was filed, the method for preparation of the antigenic TF composition that needs to remove the influential factor against the TF activity and procedure have been clearly taught in the art as evinced by EP (0 143,445). EP (0 143,445) teaches a method for removing the colostrums, casein and fat from the milk product that contains the antigenic specific TF (See entire document, especially claims 1-40).
- 11. Therefore, it would have been obvious for a person with ordinary skill in the art to be motivated by the cited reference for making the a composition comprising the HHV6A and/or HHV6B TF, wherein the other substances that influence the function of said antigenic specific TF activity are removed, in order to get the more effective and specific biological activity exhibited by said HHA6A and HHV6B antigenic specific TF.
- 12. Hence, the claimed invention as a whole is prima facie obvious absence unexpected results.

#### Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

Application/Control Number: 09/776,010

Art Unit: 1648

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BAOQUN LI, MD PATENT EXAMINER

Bao Qun Li Scrog un Li
03/19/2006

Page 5